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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	MD No. 02641 **PLAINTIFF'S MEMORANDUM RE RELEVANCY AND DISCOVERABILITY OF FDA INSPECTION AND WARNING LETTER AND RECOVERY CONE REMOVAL SYSTEM**

INTRODUCTION

On July 13, 2015, the Food and Drug Administration (FDA) issued a "Warning Letter" addressed to Timothy M. Ring, Chairman and Chief Executive Officer of C.R. Bard, listing statutory violations found at Bard Peripheral Vascular facilities in Queensbury, New York, and Tempe, Arizona. [Ex. 1.] The letter lists multiple violations of the Code of Federal Regulations (CFRs) which governs medical device companies. Initial discovery conducted into the contents and allegations of the document was via a small document production by Bard and a Rule 30(b)(6) deposition of witness Chad Modra. Witness Modra acknowledged that the citations "involve(d) multiple violations of safety processes" and that per the FDA this list of citations "is not intended to be an all-inclusive list of violations." [*See* Ex. 2, excerpts of transcript of deposition of Chad Modra ("Modra Dep."), at 440:12-17; Ex. 3, Modra Depo., at 441:4-24.]

As this Court noted at the recent Case Management Conference, this is a new MDL. In that context, Plaintiffs should be permitted to take discovery here as in any new case (subject to the general restrictions on discovery that is excessive, duplicative, or clearly disproportionate to the needs to the case). The discovery relating to the issues described as the "FDA Warning Letter" and the "Recovery Cone Removal System" is relevant to Plaintiffs' claims in this MDL, and this Court should not preclude Plaintiffs from taking discovery on those issues.

First, the FDA Warning Letter discovery involves new information. The FDA admonished Bard that it had committed multiple violations of the CFRs relating to its inferior vena cava ("IVC") filters and the Recovery Cone Removal System ("Recovery Cone"). In particular, the FDA identified eight separate categories of violations (and multiple individual violations within each category) by Bard that included, among other things, its failure to report accurately to the FDA the incidence and severity of adverse events (serious injuries and deaths) for its filters. Importantly, in response Bard took several actions, including significantly redesigning its Quality Assurance program and conducting a two-year "retrospective review" of its FDA reporting of adverse events. That review revealed that, out of 939 adverse events, Bard had misreported 274 serious injuries and deaths to the FDA as "malfunctions" – an alarming underreporting rate of nearly 30 percent of all adverse events. The results of that review further demonstrate that Bard accurately reported *less than 20 percent* of the serious injuries caused by its IVC filters.

Second, the Recovery Cone discovery includes information relating to Bard's design, manufacture, testing, marketing, and attempts to obtain FDA approval or clearance for the Recovery Cone devices – the devices that Bard marketed and sold as the single and exclusive device to remove Bard's Recovery, G2, G2X, and G2 Express IVC filters in this litigation (device models likely to make up a substantial percentage of the cases in this MDL). The FDA has concluded that Bard failed to obtain required FDA approval or clearance for the Recovery Cone, meaning that these "retrievable" IVC filters

that Bard marketed and sold to Plaintiffs and their physicians are essentially not retrievable and can only be removed through significantly more invasive surgical means.

The issues in the FDA Warning Letter, including Bard's dramatic underreporting of serious injuries and deaths, all relate to the IVC filters at issue in this suit. In medical device cases, manufacturers often argue to the jury that the FDA approved their device as safe for use. Without waiving any rights to seek preclusion of such evidence at trial, Plaintiffs are entitled to discovery to rebut any such claim, and Bard's violations of its obligations to the FDA are probative of this issue. Moreover, Bard's dramatic underreporting of its IVC filter failures demonstrates that what it told the prescribing (and implanting) physicians and the general public about the safety and effectiveness of its devices was false, misleading, and in conscious disregard for the patients' rights and safety. This evidence is at the heart of all of Plaintiffs' claims relating to the safety, efficacy, and warnings associated with every generation of Bard's IVC filters. Similarly, Bard's failure to obtain FDA approval or clearance to market the Recovery Cone is relevant to Plaintiffs' claims that Bard provided false and misleading information regarding its filters to Plaintiffs and their physicians and that Bard's overriding focus is on competitive advantage at the expense of patient safety and risk avoidance. Moreover, many Plaintiffs in this MDL, and Plaintiffs soon to be in this MDL, have claims related to the inability to retrieve Bard's so-called "retrievable" IVC filters.

This is just discovery. Whether the evidence on these issues is ultimately admissible and whether Plaintiffs are ultimately able to make out claims based on them are issues for consideration at a later time. But, for discovery purposes, their relevance to Plaintiffs' existing claims in the Master Complaint is clear. This Court should reject Bard's attempt to preclude Plaintiffs from fully discovering this relevant information.

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I. Background Facts

A. The FDA's 510(k) Process for the Clearance of Medical Devices for Sale

Before marketing and selling medical devices[1] to the public, manufacturers must obtain either "approval" or "clearance" from the FDA. It is important to properly characterize the difference between the FDA's 510(k) clearance[2] process and the far more rigorous premarket approval[3] (PMA) process. While PMAs involve extensive testing of products and vetting of the device to assess efficacy and safety risks, the FDA's 510(k) process (so named because it arises out of § 510(k) of the Food, Drug and Cosmetic Act of 1938, now codified at 21 U.S.C. § 360(k)) does not determine product safety or effectiveness. It is not even "approval" by the FDA. It merely demonstrates that the product is "cleared" for sale, based on the fact that the device is "substantially equivalent" to another product already on the market (the "predicate device"). 21 C.F.R. § 807.92(a)(3). The idea is that the "new" device is not really new at all but is only an insubstantially modified version of a medical device that is already on the market and being safely used by doctors with their patients.

Unlike the PMA process, 510(k) clearance is relatively expedited and the FDA does little in terms of review and analysis of the device – relying on the manufacturer's assertion that the proposed device is the substantial equivalent of an already approved predicate device. *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court emphasized that 510(k)

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[1] Medical devices are defined in 21 U.S.C. § 321(h) and on the FDA website at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm. Although some basic medical instruments are exempt from FDA regulation, the IVC filters at issue in this litigation are "Class II" devices which require FDA blessing before they can be marketed to the public. 21 CFR § 870.3375 (classifying "cardiovascular intravascular filter[s]" used in the inferior vena cava for purposes of preventing pulmonary thromboemboli as Class II devices).

[2] *See* 21 C.F.R. part 807, subpart E (regulations for 510(k) process); FDA website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm (Feb. 8, 2016).

[3] *See* 21 C.F.R. part 814 (regulations for PMA process); FDA website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm (Feb. 8, 2016).

clearance does not involve independent safety testing by the FDA, stating that "[t]he §510(k) process is focused on *equivalence*, not safety . . . . As a result, substantial equivalence determinations provide little protection to the public." *Id*. at 492-93.

Thus, for medical devices cleared under the 510(k) process, the public can really only rely on the good faith of the manufacturer for assurance that the device is effective and safe. For the manufacturer, this good faith includes both (a) performing and reporting appropriate, thorough pre-market testing and (b) demonstrating to the FDA with those results that the device is, in fact, substantially equivalent to an approved device on the market. It is essentially an honor system. And, this honor system continues after 510(k) clearance; after placing a medical device on the market the identification and analysis of injuries and deaths associated with its use is the manufacturer's single most important task. This information is critical in validating whether the product performs as safely and effectively as its 510(k) predicate device; it also fulfills the manufacturer's common-law duty to the public of making sure that the device is safe and effective. The FDA, likewise, must have comprehensive and accurate data regarding injuries and deaths to evaluate whether a device is performing in accord with the manufacturer's predictions in the clearance application and to make decisions such as whether to force a recall of a device producing injuries at an unacceptable and avoidable level. If manufacturers fail to report accurate data, there is little or no way for the FDA or the public to learn about health hazards associated with a 510(k)-cleared medical device.

To facilitate accurate post-market reporting, the FDA implemented and maintains the MAUDE (Manufacturer and User Facility Device Experience) database, where device manufacturers are required to report adverse events. This database is available to the public through the FDA website.[4] As stated by FDA on its website:

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[4] *See* FDA website, MAUDE - Manufacturer and User Facility Device Experience, *at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last accessed Feb. 8, 2016). MAUDE data is used by device companies to determine if their devices are performing as safely and effectively as expected, intended, and more importantly, as represented to physicians and patients. MAUDE data, coupled with IMS (company unit sales) data, provides the only available means to conduct relative risk analyses among and

> Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.[5]

In addition to the FDA, physicians and the public rely on the information reported by device manufacturers to assess the efficacy and safety of medical devices.

B. FDA Clearance of Bard Retrievable IVC Filters

In 2002, Bard sought 510(k) clearance for the Recovery IVC filter. Bard sought approval through the 510(k) process based on the Simon Nitinol Filter ("SNF") as its predicate device. The SNF was a "permanent" (or non-retrievable) filter that had been marketed in the United State since 1990. Bard distributed and marketed the SNF beginning in 1992, and continues to do so today. Bard redesigned the SNF to make it "retrievable" as the Recovery filter. On November 27, 2002, the FDA gave Bard 510(k) clearance to market the Recovery filter as a permanent filter based on the claim it was substantially similar to the SNF as its predicate device with respect to safety, efficacy, design, and materials. Bard obtained 510(k) clearance to market the Recovery filter for optional retrieval on July 23, 2003, using the permanent Recovery filter as the predicate device. Bard's stated purpose of making a retrievable filter was to increase its profits by increasing the overall market for IVC filters and Bard's percentage of said market.

Bard, however, did not obtain separate approval or clearance for the Recovery Cone as the device to retrieve the filters. As a result, Bard reached the market with a retrievable filter months in advance of its competitors, who took the time to obtain FDA clearance for their retrieval devices. Today, more than fifteen months after the FDA began its ongoing audit and investigation, Bard has still not received FDA clearance or approval to market its Recovery Cone.

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between competitive devices. Bard has been doing this analysis since shortly after the introduction of its Recovery filter to the U.S. market in 2003. [E.g.s, Exs. 4, 5, and 6.]

[5] The database has a field for type of event, which includes malfunction, serious injury, and death.

Bard subsequently redesigned the Recovery filter and submitted applications for (and obtained) 510(k) clearance for the following "retrievable" filters: G2, G2 Express (G2x), Eclipse, Meridian, and Denali. Each of these devices and their 510(k) clearance rely on the immediately preceding device as its predicate, and all trace back to the SNF.

C. Bard's Reporting to the FDA of Adverse Events

Shortly after taking the Recovery filter to market and as part of its requirements under the CFRs, Bard began making reports to the FDA of adverse events relating to its retrievable IVC filters. In accordance with the FDA reporting requirements for adverse events (and consistent with the fields in the MAUDE database), Bard had to identify each adverse event and each reported complaint as falling into one of the following categories: (a) unrelated to the product and non-reportable; (b) device malfunction (no serious injury); (c) serious injury caused by the device; and (d) death caused by the device. It then had to report to the FDA all of those falling within the latter three categories and to identify each adverse event with the category to which it belonged.

Review of the MAUDE database for the years 2004-2008 reveals that Bard's IVC filters were responsible for 50% of all adverse events; 64% of all occurrences of migration of the device; 69% of all occurrences of vena cava wall perforation; and 70% of all occurrences of filter fracture. This is true even given Bard's underreporting of events.

D. The Warning Letter

In late 2014, the FDA conducted inspections of Bard Peripheral Vascular's facilities in Queensbury, New York, and Tempe, Arizona – Bard's IVC filter facilities. Those inspections started a nine-month investigation by the FDA. Following the inspections, the FDA issued Bard "483" letters ("Inspectional Observations") in which it identified various deficiencies and violations by Bard at its facilities.

As part of the FDA's investigation, its investigator randomly audited a small sample of Bard complaint files. Even in a small sample, she discovered eight instances where serious injuries and a death had been misreported as non-injurious "malfunctions" to the FDA. She also found ten patients who had attempted surgical (not Recovery Cone)

procedures to remove their IVC filters for whom the surgical retrieval process was unsuccessful. She further found Bard's files lacked required information necessary to determine the nature of the patient injuries, the reasons for the failures, the ultimate outcomes, or the potential for future harm from these events. [Ex. 1, at 5-6; Ex. 7.]

Bard had the opportunity to respond to the 483 letters and to cure the issues; and, in fact, submitted several responses to the FDA. However, the FDA found its responses "not adequate"; Bard ultimately failed to cure the violations – forcing the FDA to issue the Warning Letter. That letter identified eight separate categories of Bard's violations of the CFRs. It advised Bard that the absence of compliance with governing regulations and failure to promptly correct these violations "may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to seizure, injunction and civil money penalties." [Ex. 1, at 10.]

Violations 1, 2, 3, 7, and 8 are particularly relevant to this MDL. Violations 1 and 2 relate to the Recovery Cone, Models RC-15 and FBRC. Specifically, the FDA found that Bard had never obtained proper approval or clearance to market these devices. *And, Violations 3, 7, and 8 identified a previously-undisclosed systemic failure by Bard to comply both with its common-law duties and regulatory to disclose relevant information.* Those violations relate to Bard's failure to appropriately investigate, report, and categorize serious injuries from its IVC filters.

E. Bard's "Retrospective Review" of Reporting after the Warning Letter

As a result of the Warning Letter (and specifically, violations 3, 7, and 8), Bard conducted a "two-year (January 1, 2013 – January 8, 2015) retrospective review of the 939 IVC Filter complaint records." [Ex. 8, at 2.] That review (reported internally on January 23, 2015) revealed, among other things, the following:

> The results of the retrospective review identified a total of 274 complaint records, which meet the definitions of Malfunction and Serious Injury as outline [sic] in 21 CFR 803. Specifically, 230 complaints were identified as requiring supplemental filing to change reportability status from Malfunction to Serious Injury and 44 complaint records were identified as requiring filing to change reportability status from non-reportable to MDR reportable.

[*Id.*] Thus, over a recent two-year period, Bard coded 230 serious injuries and deaths as malfunctions knowing full well that this is how the report would be coded in the MAUDE database. Bard also failed to report, at all, 44 additional events which should have been reported to the FDA and MAUDE. The type of injury is unknown from what Plaintiffs have received thus far, but each involves an issue of patient safety.[6]

The level of Bard's misreporting is astounding. In nearly 30 percent of the adverse events, Bard reported the severity of the event as less than what it actually was. For the vast majority of these, Bard reported serious injuries and deaths as mere "malfunctions." To give some perspective on this two-year period, a review of the MAUDE database during the same time period as Bard's retrospective review reveals that it reported a total of *66* serious injuries during that time. The "retrospective review" shows that number should have been closer to 340 – a 500% increase in reported serious injuries and deaths.[7]

What neither the FDA nor Plaintiffs know at this point is how many mistakes, incorrect or misleading reports, unreported serious injuries, and other errors are present in the internal complaint files over the 13-plus year history of marketing the entire line of SNF-based retrievable IVC filters. Extrapolating from the two-year review suggests this number is in the thousands. Obviously afraid of the outcome, Mr. Modra testified that Bard has no intention of conducting an audit of the years prior to 2013.

F. Plaintiffs' Discovery of Bard's Rampant Underreporting of Serious Injuries and Deaths and Failure to Obtain FDA Approval to Market the Recovery Cone Retrieval Device in Phase I.

Plaintiffs learned of the Warning Letter shortly after its issuance by the FDA and requested that Bard produce documents and a corporate representative to testify regarding Bard's interactions with the FDA and the issues raised in the letter. Obviously, due to the timing of the letter and the creation of this MDL, Plaintiffs had no opportunity to take that

[6] Mr. Modra initially agreed at his deposition that all 44 were likely serious injuries, but later stated he did not know. [Modra Dep. (Ex. 9) at 196:4-197:4.]

[7] The MAUDE database (as of January 1, 2016) still only lists 66 serious injuries reported by Bard during the two-year audit period. Discovery is needed to explain why Bard has not yet reported some, most, or all of the 274 serious injuries it admitted over a year ago should be reported.

discovery until the first phase of this case. At the initial case management conference in October 2015, nine months after the above-referenced internal "retrospective review," Bard claimed that the adverse events reporting violations merely involved some failures to record patient data and "a few deployment issues." [Oct. 29, 2015 Transcript of Proceedings, at 119:6-120:7.] And, significantly, coming out of that conference, Bard refused to produce anything but a limited scope of documents for the deposition.

1. The deposition and documents disclose for the first time Bard's dramatic underreporting of injuries.

Among the documents Bard did produce in advance of the Rule 30(b)(6) deposition were the 483 letters from the FDA and Bard's own "retrospective review." Bard began producing these documents one month before the deposition, for which it designated Chad Modra to testify as its representative. Those documents and Mr. Modra's testimony revealed for the first time evidence of the major flaws and inaccuracies in Bard's identification and categorization of injuries caused by their IVC filters. They also revealed for the first time Bard's systemic failure to accurately report to the FDA, and ultimately to MAUDE, the appropriate category of those injuries as discussed above.

Contrary to Bard's contention to this Court at the October 29, 2015, CMC that the "complaint handling" was only about some minor reporting errors, Bard's underreporting and misreporting of information was significantly more insidious. It demonstrates that Bard provided false and misleading information to the FDA and to the public regarding the safety of its retrievable IVC filters. Its internal review demonstrates the magnitude of this problem – 30 percent of all complaint files were underreported as to severity and Bard only reported to MAUDE 66 of the 340 (19.4%) serious injuries and deaths attributable to its retrievable IVC filters during a two-year period.

Despite these astounding results, Mr. Modra claimed that he was confident this two-year period was an isolated aberration because Bard's internal reporting provided it a clear picture of its filters and their failures, contending that he had spreadsheets that "validated" prior reporting. [*See* Ex. 10, Modra Dep., at 513:22-514:5.] He further

confirmed that Bard performs internal rate comparisons using MAUDE and IMS data (manufacturer sales data) to evaluate the relative risks of serious injuries and death between Bard's devices and those of its competitors. [Ex. 11, Modra Dep., at 536.] But Bard does not share that information with the FDA or the public (including physicians).[8] Of course, neither Plaintiffs nor their physicians who rely on the honor-code public reporting of Bard have seen Mr. Modra's spreadsheets or any validation of them. And, Bard now seeks to preclude any discovery regarding these relevant issues based on its unshared, internal tracking.

2. The deposition and documents disclose Bard's failure to obtain FDA clearance to market and to sell the Recovery Cone retrieval device.

Plaintiffs also learned through the initial documents and Mr. Modra's deposition that, according to the FDA, Bard had been selling the Recovery Cone retrieval device without FDA approval or clearance for more than 11 years. The FDA has taken issue with Bard's failure to obtain approval or clearance for the Recovery Cone, and it has required Bard to take steps to obtain such clearance. But Bard has marketed and sold the Recovery Cone as the single retrieval device for its "retrievable" Recovery, G2, G2X and G2 Express IVC filters (which will likely comprise 80+ percent of cases in this MDL) for that whole time. Bard marketed the Recovery Cone "without marketing clearance or approval," knowing that "this product is a device because it is intended for use in the diagnosis or disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body." [Ex. 1, at 2-4.] Bard does not now dispute this fact.[9] But in 2002, Bard merely produced a "memo to

[8] Bard engineer, Rob Carr, who has been involved in the research and development of Bard filters from inception, testified in the capacity of a 30(b)(6) designee that Bard's internal rate analyses are confidential and not shared with anyone outside of Bard. (*See* Ex. 12, Carr Deposition, April, 17, 2013, at 165:14-17.)

[9] Indeed, its competitors in 2003 and 2004, recognized and complied with the regulations to market only after appropriate clearance or approval. [Exs.13 and 14.]

file" in support of its actions [Ex. 15] two months *after* clearance of the retrievability indication for the filter it was manufactured and designed to retrieve.

G. Plaintiffs' Requests for Discovery Arising out of Phase I

As to the reporting, investigation, trending, tracking, and coding of serious injuries and deaths associated with its entire IVC filter line, Mr. Modra identified numerous categories of documents that related to the internal and external review and reporting of adverse events for Bard's IVC filters. Plaintiffs seek information concerning Bard's actual injury and death data and for related issues such as Bard's internal tracking, the raw data and information available to Bard, and Bard's corporate knowledge and response to those problems. These questions are at the core of Plaintiffs' claims of defect, failure to warn, misrepresentation, fraud, and punitive damages.

Plaintiffs served two document requests on Bard concerning the Warning Letter: (a) documents subpoenaed to be produced with the witness, which Bard refused to produce before the deposition, and (b) a separate request for production based upon documents identified and discussed by Mr. Modra in his deposition. [10]

In addition to written discovery, Plaintiffs seek to follow up on the deposition of Mr. Modra by examining those directly involved in these issues, including:

1. Maureen Uebelocker – Bard's Director of Quality Assurance; she reported directly to Mr. Modra during the relevant time and was responsible for the individuals who performed the reporting, tracking, and trending of adverse events.

2. Judy Ludwig – A manager in the Quality Assurance department and one of the persons responsible for FDA reporting. She was a direct report to Ms. Uebelocker.

3. John Wheeler – According to Mr. Modra, Mr. Wheeler was responsible to investigate failures, complaint files, and MDR reporting.

4. Gin Schultz – Bard's Vice President of Quality and the direct report for Mr. Modra.

[10] These are attached as Exs. 16 and 17.

5. A 30(b)(6) deposition of Bard's internal characterization, counting, trending, and reporting of injuries and deaths.

Because they were addressees of the Warning Letter and other correspondence from the FDA on these issues, Plaintiffs requested that Defendants produce the custodial files of Messrs. Ring, Williamson, and Gaede so that Plaintiffs can determine whether they were sufficiently involved in these matters to warrant their depositions. As they do not yet have the files, Plaintiffs cannot determine whether their depositions are necessary.

As to the Recovery Cone issues, Plaintiffs requested the depositions of Mary Edwards and Robert Carr. Ms. Edwards was in charge of Bard's submission of the 510(k) application for the Recovery filter, which Bard contended included the Recovery Cone retrieval device. She was also the author of the "memo to file" that concluded Bard did not need to obtain separate clearance or approval for the Recovery Cone. As such, she should have discoverable information regarding Bard's decision not to seek separate clearance or approval for the Recovery Cone.[11] Mr. Carr was the primary engineer on the Recovery filter and Recovery Cone and significantly involved in the 510(k) application for the Recovery filter. Like Ms. Edwards, he should possess information regarding Bard's original decision not to seek separate clearance or approval for the Recovery Cone.

All of this discovery is narrowly tailored to the critical information concerning the actual number of people being killed or injured by Bard filters; Bard's internal evaluation, trending, analysis, and response to that information; the truthfulness and accuracy of Bard's reporting of these injuries and deaths to the FDA; and more importantly how Bard represents the risk profile of its devices to physicians and patients.

II. The Evidence Relates to Claims in this MDL and Should Be Discoverable.

A. FDA Warning Letter

The evidence that Plaintiffs seek relating to the FDA's Warning Letter, its findings of violations by Bard, Bard's failure to report accurately the adverse events relating to its

[11] Plaintiffs also believe written discovery in the form of Requests for Production, Interrogatories, and Requests for Admissions should be served on this topic.

IVC filters, and its internal (and apparently different) tracking of those adverse events is all relevant to Plaintiffs' claims in this MDL.

In the first instance, the actual and accurate adverse event numbers are relevant to Plaintiffs' claims for product liability (Counts II and III) and negligence (Counts IV and VII). The actual failure and injury rates of Bard's products are directly relevant to the risk-benefit analysis of the products claims as well as to the reasonableness of Bard's actions in the design of those devices and the warnings it gave about them.

Bard's misreporting and underreporting of the actual failure rates and serious injuries and deaths caused by their IVC filters are relevant to Plaintiffs' claims for failure to warn (Counts II and VII), misrepresentation (Count VIII), fraudulent misrepresentation (Count XII), fraudulent concealment (Count XIII), and the various state consumer fraud and unfair/deceptive practices statutes (Count XIV). Bard's regulatory violations also support Plaintiffs' claim for negligence *per se* (Count IX).

The evidence Plaintiffs seek here proves elements of each of those claims. Technical regulatory obligations aside, the crux of Plaintiffs' case involves Bard's deceit, deception, distortion, concealment, and conscious disregard for the rights and safety of Plaintiffs and others. One need only compare the corporate-approved FAQs, as well as Bard's Crisis Communication Plan (Exs. 18 and 19), to Bard's various rate analyses which involve analyses of the data from the MAUDE database (Exs. 4, 5, and 6) to reveal the nature and extent of such conduct by Bard consistently over many years. Consider just the information already known: what impact would a 500 percent greater risk of serious injury have had on doctors and patients (not to mention the FDA)?

Additionally, Plaintiffs expect that Bard, as device manufacturers often do in these cases, will argue to the jury that it obtained clearance from the FDA to market these devices, suggesting that they are safe and reliable. Plaintiffs should have fair opportunity to rebut that argument. This discovery will allow them the opportunity to do so.

Finally, Mr. Modra suggested at his deposition that, despite its failure to report accurately to the FDA, Bard accurately tracks injury information internally – as if that

somehow relieves Bard from providing accurate information to patients and their doctors. Plaintiffs and their physicians, however, relied on Bard's reporting to the outside world. Plaintiffs should be allowed to discover both what Bard was reporting internally[12] and to the FDA and the outside world to prove Bard's failure to provide accurate information to those who make medical decisions to use Bard's IVC filters.

B. Recovery Cone evidence

Virtually every Plaintiff in this MDL was sold a Bard IVC filter as a "retrievable" device. But, as the FDA noted in the Warning Letter, Bard never obtained approval or clearance to sell that device – despite having marketed it as the sole device for such retrieval. As a result, the "retrievable" devices that Bard sold to the Plaintiffs in this MDL are, in fact, not retrievable as advertised. Instead, they may only be removed by significantly more invasive surgical procedures.

This evidence directly supports Plaintiffs' claims for product liability based on information defect (Count III) and negligent failure to warn (Count VII), misrepresentation (Count VIII), fraudulent misrepresentation (Count XII), fraudulent concealment (Count XIII), and the various state consumer fraud and unfair/deceptive practices statutes (Count XIV). Bard's failure to obtain FDA clearance for the Recovery Cone also support Plaintiffs' claim for negligence *per se* (Count IX).

III. Conclusion

This is a new MDL. Discovery should not be proactively limited on any relevant subject, and certainly not as to the one new topic that has not been the subject of discovery in any of the prior litigations. The information Plaintiffs seek relating to the FDA Warning Letter and Recovery Cone is relevant and relates directly to Plaintiffs' claims in this MDL. It goes to the core of Plaintiffs' claims and should be allowed.

[12] Indeed, the Lehmann Report, which is the subject of a separate motion before this Court, demonstrates precisely Bard's knowledge of the significantly higher rate of adverse events for its retrievable IVC filters as compared to those of its competitors.

DATED this 10th day of February 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of February, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Nancy Jo Koenes

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